State of California
Air Resources Board

Final Statement of Reasons for Rulemaking
Including Summary of Comments and Agency Responses

PUBLIC HEARING TO CONSIDER THE ADOPTION OF A REGULATORY AMENDMENT IDENTIFYING INORGANIC LEAD AS A TOXIC AIR CONTAMINANT

Public Hearing Date: April 24, 1997
Agenda Item No.: 97-3-2

I. GENERAL: UPDATE OF INITIAL STATEMENT OF REASONS

This rulemaking was initiated on March 7, 1997 by a notice of public hearing to consider the adoption of a regulatory amendment identifying inorganic lead as a toxic air contaminant (TAC) as set forth in Title 17 California Code of Regulations, section 93000. A Staff Report (Initial Statement of Reasons for Proposed Rulemaking) was made available for public inspection by March 7, 1997. The Staff Report, which is incorporated by reference herein, contained the text of the regulatory amendment as proposed by staff, along with a description of the rationale for the proposal. Accompanying the Staff Report were three technical support documents: an Exposure Assessment or "Part A"; a Health Assessment, or "Part B"; and Staff Responses to Comments, or "Part C".

On April 24, 1997, the ARB conducted a public hearing at which it received written and oral comments on the regulatory proposal. At the conclusion of the hearing, the Board adopted the regulatory amendment as proposed by adopting Resolution 97-17.

No mandates. The Board determined that this regulatory action will not result in a mandate on any local agency or school district.

Alternatives. The Board has determined that no alternative considered by the agency would be more effective and less burdensome to affected private persons than the action taken by the Board. This rulemaking is the only way available to identify inorganic lead as a TAC. The identification will not require any entity to incur costs in reasonable compliance with the rulemaking. The identification does not establish any controls for inorganic lead.

No Economic Impact. This rulemaking will have no economic impact because it merely identifies inorganic lead as a TAC. It does not establish any controls for inorganic lead. It does not require any entity to incur costs in reasonable compliance with it.

II. SUMMARY OF COMMENTS AND AGENCY RESPONSES.

Before or at the hearing, April 24, 1997, written comments were received from the Lead Industry Association (LIA), Bay Area Air Quality Management District, Children's Health Network, South Coast Air Quality Management District, Dr. Birt Harvey of Stanford University School of Medicine. At the hearing, oral testimony was presented by Tom McHenry of GNB, Inc., Jane Luxton of LIA, Dr. Alan Kaufman, and Janet Hathaway of the Natural Resources Defense Council. The commenters generally expressed support for the proposed amendment. Set forth below is a summary of each objection or recommendation specifically directed at the proposed amendment or the procedures followed in the rulemaking, along with an explanation of why the proposed amendments were not changed to accommodate the objection or recommendation. Consistent with their roles as specified in Health and Safety Code sections 39660-39662, the ARB staff has responded to comments regarding exposures to inorganic lead while the OEHHA staff has responded to comments regarding the health effects of inorganic lead. As the agency proposing this regulatory amendment, the ARB adopts OEHHA's responses and incorporates them as its own.

AIR RESOURCES BOARD STAFF RESPONSES
TO SUMMARIZED WRITTEN AND ORAL COMMENTS ON THE MARCH 1997
EXECUTIVE SUMMARY AND PART A EXPOSURE ASSESSMENT

Summarized Written Comments and Responses

I. Lead Industries Association, Inc., Battery Council International, GNB Technologies, Inc. (collectively "LIA")
April 16, 1997

Comment 1: The entire identification proceeding is unnecessary because all lead compounds have been listed as federal hazardous air pollutants (HAPs) under the federal Clean Air Act, and therefore automatically qualify as TACs since the Board formally identified all lead compounds as toxic air contaminants (TAC) under California law on April 8, 1993. The proceeding should be terminated as duplicative and unnecessary.

Response: Inorganic lead is not a compound substance; it is composed of elemental lead only. Lead compounds were identified as TACs in April 1993; the federal list of HAPs never included elemental lead. This rulemaking identifies a substance as a TAC that was not identified previously. This is neither duplicative nor unnecessary. At the April 24, 1997, hearing on this proposed resolution, the same commenter stated that it did not oppose the identification of inorganic lead as a TAC. There is ample evidence discussed in the staff report and the technical support documents indicating that inorganic lead meets the definition of a TAC. (Health and Safety Code section 39655.)

Comment 2: The reason the Air Resources Board (ARB) has continued with identifying inorganic lead as a TAC for the last four years is because of the omission of elemental lead from the federal HAP list. The omission of elemental lead was no oversight because elemental lead is a heavy, inert metal that does not present an air hazard under ambient conditions.

Response: Currently, there are no measured ambient concentrations of elemental lead. However, there are sources that emit elemental lead into the air. These include grinding operations and ranges where handguns and rifles are fired. The definition of a TAC does not require that a substance be measured in ambient air to be identified as a TAC. Any toxic substance that is discharged to the atmosphere may be identified as a TAC. (Health and Safety Code sections 39660, 39655 and 39013.)

Comment 3: Because of recent advances in measurement technology and research methodology, the recent research findings as well as current, comprehensive analyses of existing studies have tended to express greater, not less, uncertainty about the strength of the conclusions about adverse effects of low lead exposures.

Response: Please see the Office of Environmental Health Hazard Assessment (OEHHA) staff Response to Comment No. 33, below.

Comment 4: At the October 31, 1996 meeting of the Scientific Review Panel (SRP), the LIA was not permitted to present evidence, correct inaccuracies, or even speak.

Response: This comment is not directed at the proposed action or to the procedures the ARB followed in proposing or adopting the action as required by Government Code section 11346.9 (a) (3). Instead, this comment is directed at a discretionary act of the SRP. Without waiving this objection, the ARB responds as follows. Health and Safety Code section 39661 authorizes the SRP, at its discretion, to elect not to accept oral testimony at its meetings. The SRP has chosen not to accept oral testimony. The members prefer that all comments be submitted in writing so that they can be evaluated in the same way that material is usually evaluated in the scientific community. Despite the decision not to accept oral testimony, the public and other stakeholders had multiple opportunities to comment in the numerous public comment periods and workshops on the proposed identification report conducted by the ARB and the Office of Environmental Health Hazard Assessment (OEHHA). This commenter made numerous written comments that were considered by the SRP and had the opportunity to comment on this proposed rulemaking.

Comment 5: Two of the SRP members were successful in removing all the qualifying language that had been added to the staff report on the basis of new scientific evidence. Regardless of the SRP's desire to "taking this document back" to the past, California law requires reliance on the best available scientific evidence, and a return to conclusions drafted in 1993 and based on older science does not satisfy the statutory mandate.

Response: This comment is not directed at the proposed action or to the procedures the ARB followed in proposing or adopting the action as required by Government Code section 11346.9 (a) (3). Instead, this comment is directed at a discretionary act of the SRP. Without waiving this objection, the ARB responds as follows. At the SRP meetings, members of the Panel may request that changes be made to the report. In each case, the SRP and staffs of the ARB and OEHHA determine if these changes are mutually acceptable and whether they warrant additional public comment. Once the SRP has approved the report, the public then has an additional opportunity to comment again in the 45-day comment period before the substance is considered for identification by the Board at a public noticed hearing. The report contains all peer-reviewed reports up to October 1996 when the report went to the SRP for their review. OEHHA has reviewed the literature on lead exposure to date over the last few years and has determined that it supports OEHHA's scientific conclusions about the known health effects of lead. However, in response to this comment the ARB inserted a preface regarding scientific uncertainity in the staff report at the April 24, 1997 hearing to supplement an SRP-approved version of the report. The staff also incorporates its response to comment No. 4, above, by reference herein.

Comment 6: There is controversy surrounding neurodevelopment effects on children. Specifically, Dr. Birt Harvey, in a commentary published in Pediatrics in 1994, expressed concern about the lack of evidence of neuro-behavioral effects of lead at levels below 20 mg/dL. Also, research by Pocock et al. and in the WHO 1995 review provide further support for this controversy.

Response: Please see the OEHHA staff response to Comment No. 35, below.

Comment 7: Dr. Edgar Schoen writes that "evidence claiming neurobehavioral damage at low blood lead levels has been controversial and complicated by multiple confounders, small effects size, and imprecise outcome measures."

Response: Please see the OEHHA staff response to Comment No. 36, below.

Comment 8: Dr. Kaufman noted that the potential confounding factors overwhelmingly cloud the picture with respect to low level neurodevelopmental health effects, precluding the kind of firm conclusions put forward by OEHHA staff and the SRP.

Response: Please see the OEHHA staff response to Comment No. 37, below.

Comment 9: In a recent study, Dr. Needleman found that among young African-American males "lead level was positively related to verbal and full-scale IQ". These sources have been ignored by OEHHA.

Response: Please see the OEHHA staff response to Comment No. 38, below.

Comment 10: The staff report and SRP Findings do not reflect the most current, best available science which recognizes that there is "uncertainty" as to the real impact of lead on children neurodevelopment.

Response: Please see the OEHHA staff response to Comment No. 39, below.

Comment 11: There are inaccurate model projections for the number of children exceeding 10 mg/dL blood lead.

Response: Please see the OEHHA staff response to Comment No. 40, below.

Comment 12: The neurodevelopment risk assessment is inappropriately based on fractions of IQ points.

Response: Please see the OEHHA staff response to Comment No. 41, below.

Comment 13: Dr. Piomelli has concluded that the effect of an average loss of 2.6 IQ points will have on the tails of the distribution appears insignificant.

Response: Please see the OEHHA staff response to Comment No. 42, below.

Comment 14: The report's conclusions on blood pressure and cardiovascular risk assessment are also flawed. There is no mention of the uncertainty or controversy around this issue.

Response: Please see the OEHHA staff response to Comment No. 43, below.

Comment 15: Dr. Staessen noted that in his research, no association was found between blood lead and blood pressure. These findings argue against the hypothesis that current lead exposure levels are associated with excess cardiovascular morbidity and mortality caused by hypertension.

Response: Please see the OEHHA staff response to Comment No. 44, below.

Comment 16: Two recent comprehensive studies – one by the World Health Organization (WHO) and one by the American Council of Governmental and Industrial Hygienists (ACGIH) – contradict the findings of OEHHA regarding the link between blood lead and blood pressure.

Response: Please see the OEHHA staff response to Comment No. 45, below.

Comment 17: In the December 12, 1996 letter from the SRP to the ARB Chairman, the SRP set forth its views on the basis for the current federal and state ambient air lead standard and the views are mentioned in the SRP findings. There was no opportunity for the LIA to respond to this. The views are not based on full information. In 1993, an EPA panel of independent experts, the Lead Subcommittee of the National Advisory Committee on Environmental Policy and Technology (NACEPT), reviewed the federal standard and unanimously concluded that it was protective of health and needed no revision. The California standard is far more stringent than the federal standard. Additional state and air quality management district controls add further protections beyond those considered by the NACEPT.

Response: This comment is not directed at the proposed action or to the procedures the ARB followed in proposing or adopting the action as required by Government Code section 11346.9 (a) (3). Instead, this comment is directed at a discretionary act of the SRP and the ambient air lead standard. Without waiving this objection, the ARB responds as follows. The commenter had an opportunity to respond during the 45-day public comment period and is doing so in this comment. The current ambient air quality standard for lead was established in 1970. It is based on out-dated health information. New information indicates that adverse health effects can be seen that at low levels of air lead, but the ARB has no plans to revise the California ambient air quality standard for lead at this time.

Comment 18: The U.S. EPA, recognizing the changes in circumstances over time, has not sought a reduction in the ambient air standard for lead. Current levels of air lead do not contribute significantly to blood lead.

Response: Please see the OEHHA staff response to Comment No. 47, below. Also, the staff incorporates its response to comment No. 17, above, herein by reference.

Comment 19: The LIA urges the ARB to terminate the identification of inorganic lead as a toxic air contaminant as duplicative and unnecessary or modify the report to correct the statements that are inconsistent with the statutory standard of reliance on the "best available science." LIA also requests a clarification in the report in the discussions of neurodevelopmental and blood pressure effects and in the risk assessments for both of these endpoints, to make it clear that serious scientific controversy exists with respect to lead's role, particulary at low blood lead levels, and that significant uncertainties are associated with the report's conclusions.

Response: In response to industry's request, the Board asked staff to add a preface in the report that addresses these issues. At the April 24, 1997 hearing the commenter supported the identification of inorganic lead as a TAC in oral testimony. The staff also incorporates its Responses to Comments Nos. 1, 3, and 6-16, above, herein by reference.

II. Pat Leyden, Deputy Executive Officer, South Coast Air Quality Management District (SCAQMD), April 11, 1997

Comment 20: We support the ARB staff's proposal to identify inorganic lead as a toxic air contaminant under the state toxic air contaminant identification program (AB 1807). The technical support document and health assessment represent the current state of knowledge about sources of lead emissions in California and the health effects of lead.

Response: The staff agrees with this comment. The staff appreciates the support from the SCAQMD.

III. Ellen Garvey, Air Pollution Control Officer, Bay Area Air Quality Management District (BAAQMD), April 22, 1997

Comment 21: The BAAQMD acknowledges the efforts of the ARB and the OEHHA staff during the process of identifying inorganic lead as a TAC. The documents submitted are thorough and professional, and present a thoughtful picture of the health effects of lead and its possible impacts in the state. The BAAQMD is also pleased that the ARB and OEHHA staff propose the development of additional risk management guidelines.

Response: The staff agrees and appreciates the comments from the BAAQMD.

IV. Joy E. Carlson, MPH, Children's Environmental Health Network, April 23, 1997

Comment 22: The Children's Environmental Health Network supports the decision that inorganic lead be listed as a TAC so that the risk management phase can proceed. Currently there are approximately one million children with elevated blood lead levels, with an estimated 200,000 residing in California. Lead exposure comes from a variety of sources and is a potent neurotoxicant that has been scientifically documented to adversely affect the health and well being of children. Everything we can do to continue to limit and decrease lead in the environment will help the children of California.

Response: The staff agrees with these comments and appreciates the support from the Children's Health Network.

V. Birt Harvey, MD, Professor Emeritus, Stanford University School of Medicine, April 23, 1997

Comment 23: I support the removal wherever possible of environmental sources of lead. Lead has no beneficial effects for children and only does harm. The less lead in the environment the better for the health and development of children and there is no apparent threshold below which lead is not harmful to children. Action by the Board to list inorganic lead as a TAC and to follow through with regulatory controls that eliminate lead emissions would be of benefit to children.

Response: The staff agrees with Dr. Harvey's comments and appreciates his support.

Summarized Oral Testimony at the April 24, 1997, Board Hearing and Responses

I. Mr. Tom McHenry representing Lead Industries Association(LIA), the Battery Council International (BCI), and GNB Technologies, Incorporated (GNB)

Comment 24: LIA, BCI, and GNB do not oppose the listing of inorganic lead as a toxic air contaminant and urges the Board to list inorganic lead as a toxic air contaminant. They do not oppose the strict regulation of lead emissions.

Response: The staff agrees with this comment.

Comment 25: Stationary sources are not the most significant contributor of lead emissions to the air, in fact, they are a much lower contributor than any other than the other major source.

Response: The staff agrees that compared to small aircraft, stationary sources are a much smaller source of lead emissions. However, average ambient air lead concentrations near stationary sources have been shown to be as much as four times the background levels and therefore, may still present a potential public health concern.

Comment 26: The report fails to reflect the degree of uncertainty of health effects at low levels of exposure and isn't consistent with the most current scientific data.

Response: In response to this comment about the uncertainty of health effects at low levels of

exposure, the ARB has added a preface to the report that addresses this issue. However, the ARB and the OEHHA staff have used the most current scientific data up to October 1996 when the report was reviewed and approved by the SRP. The staff incorporates its Response to Ccomment No. 19, above, by reference herein.

Comment 27: It is inappropriate to use fractional I.Q. measurements and that this analysis should not make its way into risk management reports and risk management efforts by this agency, local air districts, and the U.S. Environmental Protection Agency.

Response: The ARB staff, directed by the Board, has added a preface to the report to address this issue.

II. Ms. Jane Luxton, LIA

Comment 28: LIA and members of the public were not allowed to speak at the SRP meeting when unilateral changes were made to the report.

Response: This comment is not directed at the proposed action or to the procedures the ARB followed in proposing or adopting the action as required by Government Code section 11346.9 (a) (3). Instead, this comment is directed at a discretionary act of the SRP. Without waiving this objection, the ARB responds as follows. Health and Safety Code section 39661 authorizes the SRP, at its discretion, to elect not to accept oral testimony at its meetings. The SRP has chosen not to accept oral testimony. The members prefer that all comments be submitted in writing so that they can be evaluated in the same way that material is usually evaluated in the scientific community. Despite the decision not to accept oral testimony, the public and other stakeholders had multiple opportunities to comment in the numerous public comment periods and workshops on the proposed identification report conducted by the ARB and the OEHHA. This commenter made numerous comments throughout the process that were considered by the SRP and had the opportunity to comment on the proposed rulemaking.

Also, at the SRP meetings, members of the Panel may request that changes be made to the report. In each case, the SRP and staffs of the ARB and OEHHA determine if these changes are mutually acceptable and whether they warrant additional public comment. Once the SRP has approved the report, the public then has an additional opportunity to comment again in the 45-day comment period before the substance is considered for identification by the Board at a public noticed hearing. The report contains all peer-reviewed reports up to October 1996 when the report went to the SRP for their review. The OEHHA states that none of the publications over the last few years led them to reverse their scientific conclusions about the known health effects of lead.

Comment 29: Even in draft form the information has shown up in a another state regulatory

agency's report as the basis for a new RCRA permit restriction. She further states that they (lead industry) are very concerned about misuse of the report in other regulatory areas.

Response: This comment is not directed at the proposed action or to the procedures the ARB followed in proposing or adopting the action as required by Government Code section 11346.9 (a) (3). Without waiving this objection, the ARB responds as follows. The report provides useful information on exposure and health effects of airborne lead. To address this comment, the Board requested the ARB to add a preface to the report that states that this information provides the basis for the identification of inorganic lead as a toxic air contaminant and risk management guidelines will be developed.

III. Dr. Alan Kaufman

Comment 30: There are errors in the measurements of I.Q. points and it is inappropriate to use fractional I.Q. points in the risk assessment for inorganic lead.

Response: In response to this comment, the Board directed the staff to add a preface in the report to address this issue. Further response to this comment is found in the OEHHA's response to comment No. 55 which is incorporated by reference herein.

IV. Janet Hathaway, Natural Resources Defense Council

Comment 31: The information provided in the report is the best available scientific information and there is discussion on biases and limitations of what is known in the report. She further states that adding a preface requested by the lead industry would be ambivalent to the SRP, improper, and a mistake.

Response: The staff agrees with Ms. Hathaway that the report contains the best available science. The Preface addresses the issue of uncertainty of health effects at low levels of exposure and the use of the analysis of I.Q. points should not be viewed as definitive. However, we have also included a provision in the Preface that the Preface in not intended in any way to modify the SRP's findings on the report and that it was not reviewed or approved by the SRP. Added language or not, the ARB relied on the report to designate inorganic lead as a TAC and adopt this rulemaking.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT STAFF RESPONSES TO SUMMARIZED WRITTEN AND ORAL COMMENTS ON THE MARCH 1997 EXECUTIVE SUMMARY AND PART B HEALTH ASSESSMENT

Summarized Written Comments and Responses

I. Lead Industries Association, Inc., Battery Council International, GNB Technologies, Inc. (collectively "LIA"), April 16, 1997

Comment 32: We do not oppose the identification of Inorganic Lead as a toxic air contaminant (TAC) under section 39660 of the California Health and Safety Code.

Response: The staff agrees with this comment. We appreciate that the Lead Industry Association and other groups represented by Ms. Luxton did not oppose that inorganic lead should be listed as a Toxic Air Contaminant under section 39660.

Comment 33: There is sharp controversy about those aspects of the staff's analysis that seek to establish adverse health effects from low levels exposures of lead and are inconsistent with the statutory standard of reliance on the best available scientific evidence.

Response: The staff disagrees with this comment. The health assessment and SRP findings include the most recent authoritative scientific evidence. OEHHA's risk assessment is supported by the findings of the National Academy of Science (NAS), Centers for Disease Control (CDC), and the United States Environmental Protection Agency (U.S. EPA). In the mid-1980s, when U.S. EPA required a 90% reduction in lead in gasoline, and proposed an entire ban on lead in gasoline, there was already strong evidence that the presence of lead in the blood was associated with decreases in intelligence and increases in blood pressure. Since then, more than two dozen additional papers on lead effects on IQ, and more than one dozen papers on lead effects on blood pressure, have been published in the peer reviewed literature. The vast majority of these studies support the earlier findings about the adverse health effects of lead, and indicate that these effects occur at low blood lead levels. In fact, in some of these studies, harmful blood lead levels were rarely above 10 to 15 mg/dL. While uncertainties will always exist in science, there is very strong and consistent evidence demonstrating the effect of low blood lead on these two outcomes. There is ample evidence in the Executive Summary and Part B Health Assessment that inorganic lead meets the definition of a TAC, Health and Safety Code section 39655.

Comment 34: Because of recent advances in measurement technology and research methodology, the recent research findings as well as current, comprehensive analyses of existing studies have tended to express greater, not less, uncertainty about the strength of the conclusions about adverse effects of low lead exposures.

Response: The staff disagrees with this comment. We have included dozens of studies in the Part B Health Assessment published between 1993 and 1996 which contradict this comment. In addition, we have included in the final draft of Part B all peer reviewed studies that we could find on the health effects of lead. Although there are many new studies, a vast majority of these studies simply confirm previous findings that we have reported in earlier versions of the document. While the document has been improved technically and includes additional sensitivity analysis, there is essentially no new evidence presented in this version that affects the overall conclusions. Finally, the 1995 report by the World Health Organization (WHO) was not a new analysis but a committee review, first drafted in 1991, of the evidence. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 35: There is controversy surrounding neurodevelopment effects on children. Specifically, Dr. Birt Harvey, in a commentary published in Pediatrics in 1994, expressed concern about the lack of evidence of neuro-behavioral effects of lead at levels below 20 mg/dL. Also, research by Pocock et al. and in the WHO 1995 review provide further support for this controversy.

Response: The staff disagrees with this comment. Dr. Harveys's essay in Pediatrics was written as part of a forum about universal lead screening for all children, to which Dr. Harvey is apparently opposed. It is an opinion, not a new presentation of evidence, and was not directed at the proposed rulemaking. However, Dr. Harvey did submit a comment on this rulemaking to ARB which was read into the record. In his letter he states, "I support the removal wherever possible of environmental sources of lead. Lead has no beneficial effects for children and only does harm. The less lead in the environment, the better for the health and development of children. There is no apparent threshold below which lead is not harmful to children." He goes to say that any act which removes lead from the environment is beneficial. Therefore, contrary to the assertions of the comment, Dr. Harvey would appear to fully support the listing of inorganic lead as a toxic air contaminant. Finally, contrary to this comment, there is good evidence of an association between blood lead at age one and IQ. Specifically, the Dietrich study in Cincinnati for one, shows that although the associations with IQ are higher when blood lead levels are present in 2 to 5 year olds, the presence of lead in the blood at age 1 is associated with reductions in IQ. In addition, there are over a dozen articles than show that at blood lead levels less than 20 mg/dL , there is a consistent association between blood lead and IQ.

Regarding the Pocock et al. 1994 meta-analysis, they state (page 1195) "our overall syntheses of the evidence in all 26 studies, strongly supports an adverse association between body lead burden and child's IQ." They further indicate that although it is difficult to determine a specific number, they suggest that a doubling of blood lead from 10 to 20 mg/dL associated with an average deficit in IQ of 1 to 2 IQ points. Regarding the WHO 1995 report, we agree with the conclusion that it is difficult for any one observational epidemiologic study to provide definitive

evidence of causality. However, the multiple findings of the adverse health effects of lead from several studies with widely diverse populations, along with known biologic mechanisms and plausibility, lend strong support to the likelihood of causality. While uncertainty will continue to remain, it is unlikely that all of the studies (over 30) that have found associations between blood lead and IQ were inflicted by the same confounders. Nevertheless, at the ARB hearing of April 24, 1997, the ARB added a preface to the staff report indicating that uncertainty exists at low air lead concentrations (defined here as approximately 0.02 mg/m^3) and that the estimates of the effects on IQ should not be viewed as definitive. As in all scientific inquiry, uncertainty remains about the precise magnitude of effect expected from lead exposure. The staff incorporates its Response to Comment No. 50, below, herein also. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC, Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 36: Dr. Edgar Schoen writes that "evidence claiming neurobehavioral damage at low blood lead levels has been controversial and complicated by multiple confounders, small effects size, and imprecise outcome measures."

Response: The staff disagrees that this comment affects this proposed rulemaking. Dr. Schoen made his comments as part of his argument against universal screening of children for lead. Like Dr. Harvey, he likely would have a different opinion regarding the discharging of lead into the environment. We agree that the evidence is complicated by the factors that he has outlined. However, the replication of the study findings over several different cohorts and over several different study periods is compelling evidence of an effect. Although the effects per person may be small, from a population-based level the effects would have public health significance and cannot be ignored. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 37: Dr. Kaufman noted that the potential confounding factors overwhelmingly cloud the picture with respect to low level neurodevelopmental health effects, precluding the kind of firm conclusions put forward by OEHHA staff and the SRP.

Response: The staff disagrees with this comment. Many of the 26 studies cited by Dr. Kaufman are not relevant to, and were not used in, our risk assessment. We agree that the evidence is "complicated by multiple confounders, etc." However, while many of these problems would suggest that it would be difficult to find an effect; they cannot explain the response effect of lead that has been found in dozens of studies presented in the Part B Health Assessment. It is unlikely that all of the studies that find an association between lead exposures and neurodevelopmental health effects are confounded by similar factors. In addition, errors in the measurement of IQ, like any health endpoint in an epidemiologic study, will exist. However, one must differentiate between errors in the measurement of the endpoint and errors in establishing the dose-response.

Statistical theory indicates that as long as the error in the predicted variable is random (i.e., sometimes the levels will be too high and sometimes too low) and not related to the concentration of blood lead, the estimated dose-response function will not be biased. That is, the slope relating alternative blood lead concentrations to subsequent losses in IQ will be a true reflection of the existing data. Since there is no reason to believe that graders of IQ scores changed their ratings based on whether a child had higher or lower blood lead levels, it is reasonable to accept the dose-response estimates, taken from a half dozen different studies and several different populations, as reasonable. Nevertheless, in examining very small changes in air lead (such as a movement from zero of 0.06 mg/m^3) as provided as an example in the document, the resultant IQ changes are also very small and, in a some sense, can lose meaning in terms of public policy. The ARB has added a preface to their report indicating that uncertainty exists at low air lead concentrations (defined here as approximately 0.02 mg/m^3) and that the estimates of the effects on IQ should not be viewed as definitive. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 38: In a recent study, Dr. Needleman found that among young African-American males "lead level was positively related to verbal and full-scale IQ". These sources have been ignored by OEHHA.

Response: The staff disagrees with this comment. OEHHA reviewed and included this 1996 study by Needleman, et al. In our review in Chapter 3, we include all of the evidence presented by Needleman, et al. We have stated the following: "In their study of a cohort of overtly asymptomatic boys, followed from ages 7 to 11, Needleman et al. (1996) reported that elevated bone lead levels were associated with increased risk for antisocial and delinquent behavior as measured by several different assessments: the Child Behavior Checklist and by teachers', parents' and self reports. At 11 years of age, there were significant associations between bone lead and teachers' and parents' reports of somatic complaints, anxious, aggressive and depressed behavior, and attention deficits. Over the 4 year observation period, the behavior and delinquency scores of high-lead subjects were more likely to worsen than were those of low-lead subjects. The study also reported a positive association between bone lead and IQ that was limited to African-American subjects. African-Americans with high bone lead levels and higher IQ scores (> 105), had mothers with higher IQS, more education, higher socioeconomic status, were more likely to come from two-parent families, and had fewer siblings than those with low bone lead. These findings led Needleman et al. to conclude that in this population, social factors, rather than bone lead, may have more strongly influenced IQ scores. Needleman and colleagues indicate that these were unexpected findings and suggest that measurement error or incomplete measurement of confounders may explain the positive association between bone lead and IQ in their study. However, stratified analysis revealed that, within each IQ stratum, subjects with high bone lead scored higher on a measure of antisocial and delinquent behavior, a finding that is consistent with the overall results of their study." Therefore, we have adequately covered this paper. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it

meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 39: The staff report and SRP Findings do not reflect the most current, best available science which recognizes that there is "uncertainty" as to the real impact of lead on children neurodevelopment.

Response: The staff disagrees with this comment. The SRP's Findings and our Staff Report reflect the latest scientific evidence. In fact, scientific papers published after the SRP Findings and ARB hearings continue to support the evidence as presented in the staff paper. There is no new evidence indicating that lead is safe for children to inhale and swallow. The evidence that the comment is referring to apparently consists of 1995 consensus report by WHO for which drafts were written over 5 years ago. As such, this report does not reflect the latest and best science. Finally, our staff report repeatedly indicates the areas of uncertainty in our assessment of the scientific evidence. In addition, when quantitative assessments are offered, confidence intervals bounding the uncertainty are provided. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 40: There are inaccurate model projections for the number of children exceeding 10 mg/dL blood lead.

Response: The staff disagrees with this comment. Rather than opposing the model projections specifically, which are accurate, the commenter seems to be disagreeing with the assumptions about some of the model inputs, specifically the mean blood lead of the population. We have used the best available published data most representative of the California population, data from National Health and Nutrition Examination Surveys (NHANES) III. Other data exist that provide both higher and lower estimates of the geometric mean of children's blood lead in California. For example, one study of children from an HMO shows only 2% of the children below age 6 have blood lead levels above 10 mg/dL. Another study using HMO data, suggests means similar to NHANES III. Finally, data from high risk census tracts in Los Angeles, Oakland, and Sacramento collected by the California Department of Health Services (CDHS) in 1987-1989, indicate that from 14 to 67% of the children have levels above 10 mg/dL. Clearly, one needs to be concerned about the representativeness of the data for communities as well as the state. For example, clinic-based samples might have a greater proportion of healthy children (with lower blood lead levels) than population based samples such as NHANES III or the CDHS study of "high risk" communities. This could result in a substantial downward bias in the estimated prevalence of children with blood lead concentrations at or above the CDC's level of concern. Finally, the prevalence discrepancies might be explained by a continuing trend of declining lead levels, although lower levels found by one study at a later date is not evidence, in itself, of such a trend. Most importantly OEHHA's sensitivity analysis indicates that the increase in children above 10 mg/dL from current (or zero) air levels is relatively robust to assumptions about the geometric

mean and standard deviation. Regardless of the actual mean blood concentrations, two things are important to note. First, one of our IEUBK models includes the case where 4.8% of the children are above 10 mg/dL, a number compatible with the second phase of NHANES III. This model indicates that increases in air lead will still quickly move large segments of the population above 10 mg/dL. Second, our sensitivity analysis indicate that different assumptions about the mean level will not impact the overall results. That is, using the aggregate model, differences in the mean and standard deviation will not change the overall results. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 41: The neurodevelopment risk assessment is inappropriately based on fractions of IQ points.

Response: The staff disagrees with this comment. The primary focus of our risk assessment is in estimating how alternative air lead concentrations will impact the number of children that move above a blood lead level of 10 mg/dL, the CDC level of concern. We have also provided evidence of dose-response functions from several studies linking changes in IQ points to changes in blood lead. In examining very small changes in air lead (such as a movement from zero to 0.06 mg/m^3) as provided as an example in the document, the resultant IQ changes are also very small and, in a some sense, can lose meaning in terms of public policy. The ARB has added a preface to their report indicating that uncertainty exists at low air lead concentrations (defined here as approximately 0.02 mg/m^3) and that the estimates of the effects on IQ should not be viewed as definitive. It should be noted however, that larger increases in air lead would likely result in larger (and potentially non-fractional) losses in IQ. In addition, on a population-wide basis, the entire distribution of IQ levels could be shifted downward. This would result in more children below the level that might be termed as clinically retarded. Therefore, on a population-wide basis, even small changes in air lead may result in changes that have public health significance. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 42: Dr. Piomelli has concluded that the effect of an average loss of 2.6 IQ points will have on the tails of the distribution appears insignificant.

Response: The OEHHA staff report only indicates what the quantitative changes will be in the resultant distribution of blood leads. The issue of what is significant will be determined by the risk managers.

Comment 43: The report's conclusions on blood pressure and cardiovascular risk assessment are also flawed. There is no mention of the uncertainty or controversy around this issue.

Response: The staff disagrees with this comment. In our document, we have included all of the peer reviewed literature that was available and many opinions on this issue are presented. Even though controversy remains, in view of the weight of positive evidence, the risks cannot be assumed to be zero. We have employed confidence intervals and utilized software packages that propagate the uncertainties in the multiple models in order to indicate the uncertainty in the estimates. This is standard procedure in epidemiology. We have reviewed all of the studies and discussed the shortcomings involved with this research. Several reviews, including the National Research Council (1993) and the U.S. EPA (1990) suggest that the evidence is overwhelming. For example, as we indicated in our document, the NRC states, "Overall, a considerable majority [of the studies] reported significant associations. Combined with the strong animal model, mechanistic results, and the moderate concordance of effect size, this suggests overwhelming evidence for the causality of the association" (page 77). This was also the consensus of the International Conference on Lead and Blood Pressure (Victery et al., 1988). The U.S. EPA concurred with this finding in the Supplement to the 1986 Addendum to the document on the Air Quality Criteria for Lead (EPA, 1990). After indicating that it is difficult for observational studies in and of themselves to definitely establish causality, they argued that a causal association is plausible given: "(1) the consistency of the significant associations found by numerous independent investigators for a variety of study populations, and (2) extensive toxicological data discussed in the 1986 Addendum which clearly demonstrated increases in blood pressure for animal models under well-controlled experimental conditions" (page 9). Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 44: Dr. Staessen noted that in his research, no association was found between blood lead and blood pressure. These findings argue against the hypothesis that current lead exposure levels are associated with excess cardiovascular morbidity and mortality caused by hypertension.

Response: Dr. Staessen's research is one of the few studies (of approximately a dozen) that has failed to find an association between blood lead and indicators of cardiovascular morbidity including changes in diastolic or systolic blood pressure or hypertension. Many others have found the association. While it is true that Dr. Staessen's findings argue against the hypothesis, many other studies show strong associations between blood lead and blood pressure. In addition, the biological mechanism for this effect has been demonstrated in animals, making it quite plausible. Finally, there is a possibility of some confounding in Dr. Staessen's work because of a "healthy worker" effect. The workers in his sample had higher blood leads, but appear to have been more healthy than the general population. Also, in a recent meta-analysis from Staessen et al. (1995), a doubling in blood lead in males was associated with a small but consistent rise in systolic (1.2 mm Hg) and diastolic pressure (0.5 mm Hg). Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 45: Two recent comprehensive studies – one by WHO and one by the American Council of Governmental and Industrial Hygienists (ACGIH) – contradict the findings of OEHHA regarding the link between blood lead and blood pressure.

Response: The staff disagrees with this comment. The ACGIH (1995) review paper, prepared as part of the update of the lead Biological Exposure Index, reviewed three older studies that reported small but significant associations between blood lead and systolic and diastolic blood pressure. While the effects per unit are small, the exposed population is large. The report recommended that confounding should be examined to more accurately define the relationship between lead and blood pressure. Two recent meta-analyses have attempted to resolve such issues. Staessen et al. (1995) found that a doubling in blood lead in males was associated with a small but consistent rise in systolic (1.2 mm Hg) and diastolic pressure (0.5 mm Hg). This association was found in spite of the fact that the authors pooled diverse populations (males, females, ages 10-88 years, occupational and non-occupational cohorts) and counted multiple findings of the same cohorts as separate studies, factors that would be expected to weaken the association. Also Schwartz (1995) found an association between blood lead and blood pressure after considering over a dozen studies within a meta-analysis. As stated above, in contrast to the WHO IPCS document, the National Research Council (NRC) of the National Academy of Sciences (1993) stated: "Overall, a considerable majority [of studies on blood lead and blood pressure] reported significant associations. Combined with the strong animal model, mechanistic results, and the moderate concordance of effect size, this suggests overwhelming evidence for the causality of the association." Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 46: There are other problems of concern. Specifically, the SRP's conclusion that the current standard of 1.5 mg/m^3 is not health protective is in error.

Response: This comment is not directed at the proposed action or to the procedures the ARB followed in proposing or adopting the action as required by Government Code section 11346.9 (a) (3). Instead, this comment is directed at a discretionary act of the SRP. Without waiving this response, the OEHHA responds as follows. Issues related to the revision of the national or state ambient standard for lead are beyond the scope of this proposed rulemaking. Furthermore, the SRP findings are not part of the OEHHA health risk assessment on lead. The staff disagrees with this comment. We do document the impact of this air lead concentration on the percent of children that will be above 10 mg/dL blood lead. It has been stated that the revision of the national lead standard the commenter refers to may not be necessary because lead has become more of a "hot spot" issue within certain areas. It should be noted that currently 4 to 10 percent of the nation's children are above the CDC level of concern of 10 mg/dL of lead in their blood. Therefore, it is reasonable and prudent public policy to minimize the additional exposures to lead for this population. Therefore, if Scientific Review Panel's concern was to minimize additional exposure to lead, it seems reasonable. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC

Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 47: The U.S. EPA, recognizing the changes in circumstances over time, has not sought a reduction in the ambient air standard for lead. Current levels of air lead do not contribute significantly to blood lead.

Response: The staff disagrees with this comment. Since the reduction of lead in gasoline, ambient levels of lead in the air have declined below the national ambient air standard for lead. Although lead in the ambient air is, on average, a minor contributor to current blood lead levels, air lead in "hot spot" or local areas can result in increases in blood lead that have public health significance. Therefore, it is necessary to identify lead as a toxic air contaminant and allow risk managers to make decisions as to what risk is acceptable in their community. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment. The staff incorporates it response to Comment No. 46, above.

Comment 48: The Air Resources Board should terminate this proceeding or modify the report to correct statements that are inconsistent with the statutory standard of "best available science". At a minimum, the report requires clarification to make it clear that serious scientific controversy exists.

Response: OEHHA has relied on the best available science, backed by hundreds of articles from the peer reviewed literature, to conclude that lead should be identified as a toxic air contaminant. Throughout the report, we have indicated the areas of uncertainty and provided confidence intervals for all quantitative estimates of risk. A preface to the report has also been added to indicate that there is inherent uncertainty involved in assessing the risks of a toxic chemical. However, it is incorrect to state that serious controversy exists regarding the need to identify lead as a toxic air contaminant. In fact, several representatives of the Lead Industry Association have stated that they do not oppose the identification of lead as a toxic air contaminant under section 39660 of the California Health and Safety Code. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment. The staff incorporates its Response to Comment No. 33, above, herein also.

Summarized Oral Testimony at the April 24, 1997, Board Hearing and Responses

I. Tom McHenry on Behalf of the Lead Industry Association, the Battery Council International, and GNB Technologies, Inc. on April 24, 1997

Comment 49: We are not opposed to listing inorganic lead as a Toxic Air Contaminant. However, we feel that the lead document fails to reflect the degree of uncertainty of the health

effects of low levels of lead. We think that the October 31, 1996 Scientific Review Panel (SRP) version did a better job of indicating this uncertainty.

Response: We appreciate that the commenters do not oppose inorganic lead's listing as a Toxic Air Contaminant under AB 1807. The SRP specifically directed the staff to remove several qualifiers that had been added to the SRP draft document (from the previous draft that they reviewed) concerning health effects of lead based on the fact that: (1) the effects of lead are well documented even at relatively low blood lead levels (around 10 mg/dL); (2) more recent evidence since the SRP's last review of the document mostly tended to support previous conclusions about lead's health effects; and (3) the evidence for both neurodevelopmental effects in children and cardiovascular effects in adults fails to identify a threshold level. Nevertheless, at the hearing of April 24, 1997, the ARB added a preface to their report indicating that uncertainty exists at low air lead concentrations (defined here as approximately 0.02 mg/m^3) and that the estimates of the effects on IQ should not be viewed as definitive. The Preface adequately addresses uncertainties in the lead document. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment. The staff incorporates its Response to Comment No. 5, above, herein by reference also.

Comment 50: According to the Health and Safety Code, Section 39662, the recommendations for toxic air contaminants must be health protective and consistent with current scientific data. The document does not fulfill the latter requirement.

Response: The staff disagrees with this comment. The risk assessment on lead includes all peer reviewed publications that we could find up to the time of issuance of the report to the SRP in late October, 1996. None of the publications over the last few years would lead us to reverse our scientific conclusions about the known health effects of lead. In fact, the vast majority of the new studies) over the last few years either support the findings of earlier studies of known health effects or indicate the possibility of additional health effects or health effects at even lower levels than previously reported. Several of the recent articles are actually reanalyses of data from previous studies and do not contain additional information that is not already included in the lead document.

II. Jane Luxton, Lead Industry Association, April 24, 1997

Comment 51: OEHHA relies on 3 sources for their conclusions on the neurodevelopment effects of lead on children: U.S. EPA, 1986, NAS, 1993; and CDC, 1991. The controversy has grown since then and this is not reflected in the document. Specifically, a 1995 report by the World Health Organization (WHO) states: "It is a matter of debate and conjecture as to the extent to which these four issues (chance, confounders, reverse causality, and selection bias) should inhibit

claims of a causal relationship in the prospective studies" and "Observational epidemiology cannot provide definitive causality".

Response: The staff disagrees with this comment. Our review of the effects of lead on neurodevelopment did not end with the 1993 NAS report, which was a review of the evidence to date. We have included dozens of additional studies published after that date. An overwhelming majority of the recent studies support the original findings that blood lead concentrations, at or near 10 mg/dL blood lead, are associated with neurodevelopment effects in children. The WHO report was originally drafted in 1991 and, like all commission reports, is based on compromise among participants. This report does not present any new scientific evidence but seeks to provide a review of preexisting studies. We agree that there is debate among some of the scientific community (and we have reported the published articles indicating this debate) about how to interpret some of these studies and the role that factors such as confounding will play. In general, observational epidemiology can never provide definitive causality. However, given the weight of evidence, the multiple studies indicating similar outcomes, the known biologic mechanism, and the evidence from occupational studies at higher blood lead levels, there is ample scientific grounds to believe that a causative relationship exists. Nevertheless, at the ARB hearing of April 24, 1997, the Executive Board added a preface to their report indicating that uncertainty exists at low air lead concentrations (defined here as approximately 0.02 mg/m^3) and that the estimates of the effects on IQ should not be viewed as definitive. As in all scientific inquiry, uncertainty remains about the precise magnitude of effect expected from lead exposure. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 52: Dr. Birt Harvey as quoted in Pediatrics in February, 1994, says that the evidence for an association between blood lead and IQ is lacking at levels under 20. Therefore, the association is much more uncertain than is portrayed in the document.

Response: The staff disagrees with this comment. Dr. Harveys's opinion essay in Pediatrics was written as part of a forum about universal lead screening for all children, about which he is opposed; instead, he favors targeted screening. In his editorial, Dr. Harvey does not provide any specific references to support his assertion that there is a lack of evidence that blood lead levels at age 1 year cause a clinically important decrease in intelligence and an increase in neurobehavioral problems by the time a child enters school. Although he does not further elaborate on this point in this editorial, he is most likely referring to clinically detectably effects in an individual child. His position is actually not much different that OEHHA's and is clarified in a subsequent commentary (Pediatrics, 1997; 11:384-388), where Dr. Harvey states: "Meta-analyses suggest that the impact on IQ in an individual child is minimal. Young children with BLLs [blood lead levels] about 10 mg/dL tend to have clinically insignificant higher IQS
(1 to 3 points) than young children with BLLs [blood lead levels] about 20 mg/dL)." He then goes on to caution: "Implications of slight changes in BLLs in individual children and in large populations are different. Although for an individual child the impact may be minimal, on a large population basis an IQ decrease of a few points or a slight increase in behavioral problems can produce important societal effects." Contrary to his assertion in the 1994 editorial, there is evidence of an association between blood lead at age one and IQ. Specifically, the Dietrich study

in Cincinnati for one, shows that although the associations with IQ are higher when blood lead levels are for 2 to 5 year olds, blood lead at age 1 is associated with reductions in IQ. In addition, there are over a dozen articles than show that at blood lead levels less than 20 mg/dL, there is a consistent association between blood lead and IQ. Dr. Harvey makes the following statement in his 1994 editorial: "Lead is a poison, and the less of it in the bodies of growing children the better." He submitted a letter to ARB, on April 23, 1997, which was read into the record. In the letter he states, "I support the removal wherever possible of environmental sources of lead. Lead has no beneficial effects for children and only does harm. The less lead in the environment, the better for the health and development of children. There is no apparent threshold below which lead is not harmful to children." He goes to say that any act that we take which removes however much lead is in the environment is beneficial. Therefore, contrary to the implications of the comment, Dr. Harvey would appear to fully support the listing of inorganic lead as a toxic air contaminant. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment. The staff incorporates its Response to written Comment No. 35, above, herein also.

Comment 53: The report has failed to take into account new scientific techniques. For example, ambulatory (not stationary) blood pressure monitoring is being used to examine the association between blood lead and blood pressure.

Response: The staff disagrees with this comment. We agree that the field of blood pressure monitoring, as with other scientific disciplines, is constantly changing. We have summarized all the studies that were available regarding the association between blood lead and blood pressure, including one that utilized ambulatory blood pressure monitoring. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

Comment 54: The report fails to acknowledge that there is scientific controversy surrounding the existence of a link between blood lead and cardiovascular disease.

Response: The staff disagrees with this comment. In our document, we have included all of the peer reviewed literature that was available and many opinions on this issue are presented. Several reviews, including the National Research Council (1993) and the U.S. EPA (1990) suggest that the evidence supporting a relationship between blood lead and cardiovascular effects in adults is overwhelming. Furthermore, while individual studies by some authors may have failed to find effects (Staessen et al., 1996), meta-analyses have revealed an association between blood lead and blood pressure (Staessen et al., 1995). At the hearing of April 24, 1997, the ARB added a preface to their report indicating that uncertainty exists regarding potential health effects (including cardiovascular effects in adults) at low air lead concentrations (defined here as approximately 0.02 mg/m^3). The Preface adequately addresses uncertainties raised by the comment. Regardless, there is ample other evidence of the adverse health effects of lead which

demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

III. Dr. Alan Kaufman, on Behalf of the Lead Industry Association on April 24, 1997

Comment 55: There are errors in the measurement of IQ. Fractional IQ changes should not be used.

Response: The staff disagrees with this comment. Errors in the measurement of IQ, like any health endpoint in an epidemiologic study, will exist. However, one must differentiate between errors in the measurement of the endpoint and errors in establishing the dose-response. Statistical theory indicates that as long as the error in the predicted variable is random (i.e., sometimes the levels will be too high and sometimes too low) and not related to the concentration of blood lead, the estimated dose-response function will not be biased. That is, the slope relating alternative blood lead concentrations to subsequent losses in IQ will be a true reflection of the existing data. Since there is no reason to believe that graders of IQ scores changed their ratings based on whether a child had higher or lower blood lead levels, it is reasonable to accept the dose-response estimates, taken from a half dozen different studies and several different populations, as reasonable. Nevertheless, in examining very small changes in air lead (such as a movement from zero of 0.06 mg/m^3) as provided as an example in the document, the resultant IQ changes are also very small and, in a some sense, lose meaning in terms of public policy. The ARB has added a preface to their report indicating that uncertainty exists at low air lead concentrations (defined here as approximately 0.02 mg/m^3) and that the estimates of the effects on IQ should not be viewed as definitive. It should be noted however, that larger increases in air lead would likely result in larger (and potentially non-fractional) losses in IQ. In addition, on a population-wide basis, the entire distribution of IQ levels could be shifted downward. This would result in more children below the level that might be termed as clinically retarded. Therefore, on a population-wide basis, even small changes in air lead may result in changes that have public health significance. Regardless, there is ample other evidence of the adverse health effects of lead which demonstrates that it meets the regulatory definition of a TAC Health and Safety Code section 39655. This evidence is discussed in the Executive Summary and the Part B Health Assessment.

IV. Janet Hathaway, Natural Resources Defense Council, April 24, 1997

Comment 56: There will rarely be total certainty regarding a scientific question like the effects of lead on children and adults since science is always evolving. However, enough is known now about lead to declare it a toxic air contaminant.

Response: The staff agrees with this comment. We agree that the scientific understanding about the effects of lead continues to evolve. We also acknowledge that there is a great deal of current information available about the health effects of lead based on epidemiologic studies, occupational exposure studies, toxicological experiments, and human clinical research. Based on the currently available science, therefore, we have recommended that lead be declared a toxic air contaminant. The ARB adopted our recommendations and voted so on April 24, 1997.